

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application No. 09/693,121

Applicant: Jeffrey Schlom

Filed: October 20, 2000

TC/AU: 1643

Examiner: Christopher H. Yaen

Docket No.: 701319 (Client Reference No. E-200-1990/4-US-06)

Customer No.: 45733

Title: **GENERATION OF IMMUNE RESPONSE TO PROSTATE-SPECIFIC ANTIGEN (PSA)**

DECLARATION UNDER 37 C.F.R. § 1.131

We, Jeffrey Schlom and Dennis Panicali, hereby declare the following:

1. We are co-inventors in the above-captioned patent application.

2. Prior to August 11, 1993, we had conceived of a method for generating a cytotoxic T-cell eliciting immune response to prostate specific antigen (PSA) in a human host, by first administering a pox virus vector containing an insertion site for DNA encoding PSA or a cytotoxic T-cell eliciting epitope thereof and then administering an additional PSA or T-cell eliciting epitope thereof.

3. Exhibit A is a Material Transfer Agreement (MTA). While the date of the MTA has been redacted, we executed the MTA prior to August 11, 1993. The MTA demonstrates that we intended to use recombinant vaccinia and fowlpox vectors with a human tumor-associated antigen gene inserted therein to produce clinical grade vaccine.

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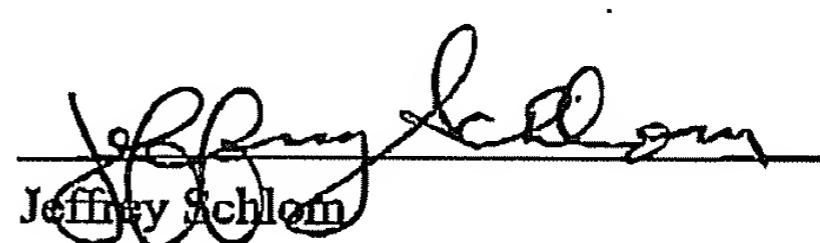
4. Exhibit B is another Material Transfer Agreement (MTA). Again, while the date of the MTA has been redacted, we executed the MTA prior to August 11, 1993. The MTA demonstrates that we intended to use a prostate specific antigen (PSA) clone in the production of clinical grade vaccine.

5. Exhibit C constitutes relevant portions of an Agenda for a site visit at the Laboratory of Tumor Immunology and Biology. While the date recited in this document has been redacted, the site visit was scheduled prior to August 11, 1993. Studies involving the use of rV-PSA in nonhuman primates are detailed on page 40 of this document. These studies include implementation of a "prime and boost" strategy. As stated in the document, "We will prime mice who have a palpable tumor with rV-PSA and then boost with varying concentrations of either bV-PSA or immunogenic PSA peptides emulsified with DETOX or liposomes." We planned on studying the growth of the tumor and the effect on cell mediated responses such as PSA specific lymphoproliferative responses and cytotoxic T cell responses. Exhibit C further sets forth our plan to utilize recombinant avipox-PSA and recombinant PSA protein to induce the generation of CD4⁺ and/or CD8⁺ T cells.

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6. We hereby declare that all statements made herein of our own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 10 - 4 - 07


Jeffrey Schлом

Date: _____

Dennis Panicali